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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

7590

09/26/2002

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EXAMINER

NGUYEN, HELEN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/26/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,168

Applicant(s)

ISHIKAWA ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The request for Continue Prosecution Application (CPA) of paper no. 10 filed July 24, 2002, is acknowledged.

The preliminary amendment of paper no. 11, filed July 24, 2002, is acknowledged.

Claims 21 and 22 are newly added.

Claims 1-22 are pending and presented for examination with elected species B, drawn to water-soluble dietary fiber.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Co-operation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claim rejection- 35 USC § 112

In view of the preliminary amendment of paper no. 11, the rejection under 35 U.S.C. 112, first paragraph set forth in the previous office action of paper no. 9, filed January 24, 2002, has been considered, but they are not persuasive. Therefore, the rejection under 35 U.S.C 112, first

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paragraph is maintained and new ground of rejection is applied for the

reasons as follows:

❖ The following is a quotation of the **first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants claim a dietary fiber, however nowhere in the specification is disclosed any example of a specific dietary fiber.

Applicants argue that dietary fibers are well-known in the art. However,

Applicants argument is merely opinion.

❖ The following is a quotation of the **second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "suspended stock solution" is vague. It is unclear as to what suspended and what in solution.

Claim rejection- 35 USC § 103

The rejection of claims 1-20 of record under 35 U.S.C. 103 (a) is made moot in view of the preliminary amendment of paper no. 11, filed July 24, 2002. However, a new ground of rejection is applied for the reasons as follows:

- ❖ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Miskel et al. (US Patent No. 3,851,051) in view of Tanner et al. (US Patent No. 5,569,466).

Miskel et al., see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

Further, Miskel et al., see Example 50, teach a soft capsule comprising a water-soluble dietary fiber (apple pectin), a material of limited oil-solubility (glycerin) and a fat and oil material or oil-soluble material (vitamin E).

Lastly, Miskel et al., see Example 43, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil-solubility (sodium saccharin). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

However, Miskel et al. do not teach a homogenous mixture of the medicinal liquid in the soft capsule.

Tanner et al. teach fill compositions for soft gel capsules (title) comprising an active agent dissolved or suspended in a carrier liquid

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(abstract). Tanner et al. teach homogenization of actives and solubilizing agents (column 4, lines 47-50, and 65-66). Water is disclosed (column 3, line 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a soft gel capsule comprising citrus pectin, to achieve high stability in view of Miskel et al.

As to the claimed homogenization, Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule. One of ordinary skill in the art would recognize that homogenization provides a stable mixture.

Conclusion

Claims 1-22 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Padmannabhan Sreenivasan can be reached at (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

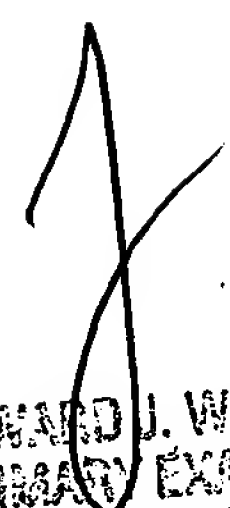
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Helen Nguyen
Patent Examiner

September 20, 2002



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PRIMARY EXAMINER
GROUP 1500